

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

In re Sitagliptin Phosphate ('708 & '921) Patent Litigation

C.A. No. 19-md-2902-RGA

MERCK SHARP & DOHME CORP.

Plaintiff,

vs.

ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD.,

Defendants.

C.A. No. 19-314-RGA

PUBLIC VERSION FILED: September 28, 2021

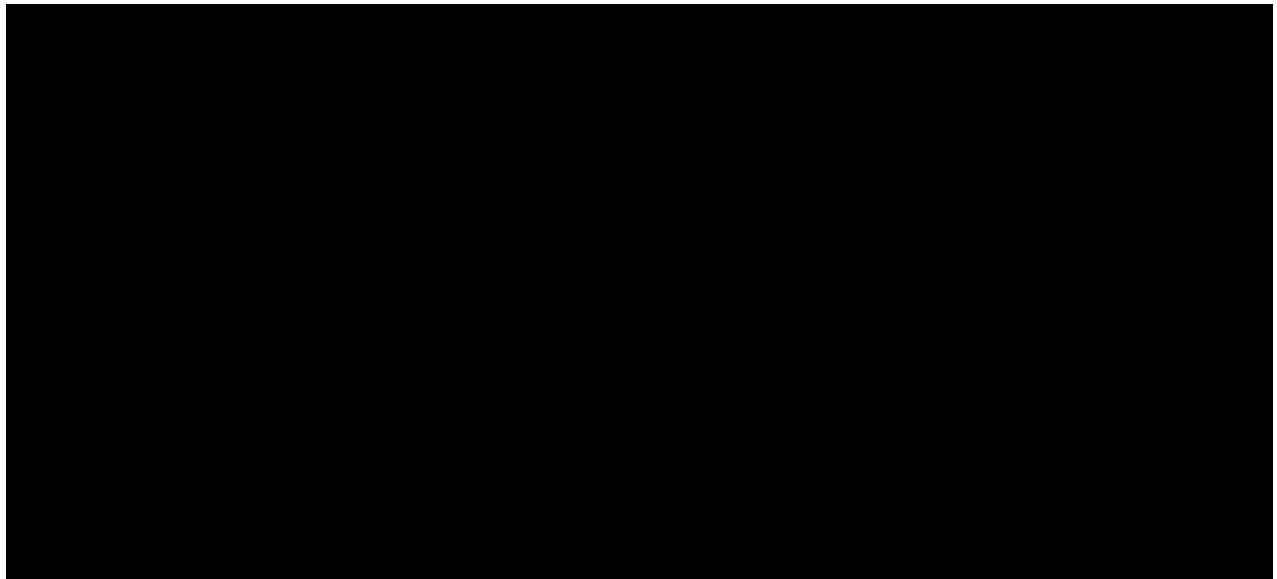
STIPULATION AND [PROPOSED] ORDER OF DISMISSAL

For the reasons set forth below, Plaintiff Merck Sharp and Dohme Corp. (“Merck”) and Defendants Zydus Pharmaceuticals (USA) Inc. (“Zydus”) and Cadila Healthcare Limited (“Cadila”) respectfully submit this Stipulation of Dismissal.

1. Zydus is the holder of Abbreviated New Drug Applications (“ANDAs”) Nos. 208186 (sitagliptin tablets 25 mg, 50 mg, and 100 mg); 208535 (sitagliptin and metformin HCl tablets, 50 mg/500 mg and 50 mg/1000 mg); and 209573 (sitagliptin and metformin HCl extended-release tablets, 50 mg/500 mg, 50 mg/1000 mg, and 100 mg/1000 mg).

2. At the time of filing ANDA Nos. 208186, 208535, and 209573, all contained certifications pursuant to 21 U.S.C. 355(j)(2)(a)(iv) (“Paragraph IV certifications”) with respect to U.S. Patent No. 7,326,708 (“the ’708 patent”) stating that the ’708 patent is invalid and/or would not be infringed by the products described in the ANDAs and seeking approval of the ANDAs before expiration of the ’708 patent.

3. On February 13, 2019, Merck filed suit against Zydus and Cadila for infringement of the '708 patent pursuant to 35 U.S.C. § 271(e)(2) based on the inclusion of the Paragraph IV certifications in the ANDAs in Civil Action No. 19-314-RGA ("the Action"). The Action was later consolidated with other suits involving the infringement and validity of the '708 patent in the multidistrict action titled *In re Sitagliptin Phosphate ('708 & '921) Patent Litigation*, 19-md-2902-RGA.



6. Therefore, subject to the Court's approval, the parties hereby agree and stipulate that all claims, counterclaims, affirmative defenses, and demands in the Action are dismissed without prejudice and without costs, disbursements, or attorney's fees.

Dated September 28, 2021

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Hon. Richard G. Andrews U.S.D.J.

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